UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF ILLINOIS

EASTERN DIVISION

BALA PALANISAMY, Individually and on Behalf of All Others Similarly Situated, Plaintiff, vs. BIOSANTE PHARMACEUTICALS, INC. and STEPHEN M. SIMES, Defendants.	)	No. CLASS ACTION DEMAND FOR JURY TRIAL

COMPLAINT FOR VIOLATION OF THE FEDERAL SECURITIES LAWS

INTRODUCTION

1. This is a securities class action on behalf of all persons who purchased or otherwise acquired the securities of BioSante Pharmaceuticals, Inc. ("BioSante" or the "Company") between February 8, 2010 and December 15, 2011, inclusive (the "Class Period"), against BioSante and its Chief Executive Officer ("CEO") for violations of the Securities Exchange Act of 1934 (the "1934 Act").

2. BioSante is a specialty pharmaceutical company focused on developing products for female sexual health and oncology. Over the past decade, BioSante has been in the process of developing LibiGel, a drug designed to improve the sex drive of women suffering from female sexual dysfunction ("FSD"), and specifically hypoactive sexual desire disorder ("HSDD").

3. During the Class Period, defendants issued materially false and misleading statements regarding the Company's commercial viability, effectiveness, and market potential for LibiGel. Defendants boasted about LibiGel's efficacy over placebo, and provided supposedly concrete "data" regarding the drug's "statistically significant" effect on increasing the "number of satisfying sexual events" for women suffering from HSDD. These purportedly positive clinical trial results furthered defendants' claims of LibiGel being "the most clinically advanced pharmaceutical product in the U.S." Defendants raised investors' expectations by analogizing the female market for LibiGel to the male market for erectile dysfunction, quoting an over $2 billion market, and comparing LibiGel to such blockbuster drugs as Viagra, Levitra, and Cialis. As a result of these false statements, BioSante's stock traded at artificially inflated prices during the Class Period, reaching a high of $3.81 on July 12, 2011.

4. On December 14, 2011, BioSante issued a press release disclosing for the first time to investors that LibiGel failed to yield positive results in large-scale efficacy tests designed by the Company. According to the clinical trial results, women treated with LibiGel did not experience a

statistically significant increase in either total satisfying sexual encounters or sexual desire. In fact, in the double-blind, placebo-controlled trial, LibiGel did not fare significantly better than the placebo.

5. On this news, BioSante's stock collapsed $1.64 per share to close at $0.48 per share on December 15, 2011, a one-day decline of 77% on volume of nearly 50 million shares.

6. The true facts, which were known by the defendants but concealed from the investing public during the Class Period, were as follows:

(a) LibiGel's efficacy was well short of that required to obtain Food and Drug Administration ("FDA") approval; and

(b) LibiGel failed to yield statistically superior results to placebo.

7. As a result of defendants' false statements, BioSante's stock traded at artificially inflated levels during the Class Period. However, after the above revelations seeped into the market, the Company's shares were hammered by massive sales, sending them down over 87% from their Class Period high.

JURISDICTION AND VENUE

8. Jurisdiction is conferred by §27 of the 1934 Act. The claims asserted herein arise under §§10(b) and 20(a) of the 1934 Act and SEC Rule 10b-5.

9. Venue is proper in this district pursuant to §27 of the 1934 Act. Many of the false and misleading statements were made in or issued from this district.

10. BioSante maintains its principal executive office at 111 Barclay Boulevard, Lincolnshire, Illinois 60069. Certain of the acts and conduct complained of herein, including the dissemination of materially false and misleading information to the investing public, occurred in this district.

11. In connection with the acts and conduct alleged in this complaint, defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including, but not limited to, the mails and interstate wire and telephone communications.

PARTIES

12. Plaintiff Bala Palanisamy purchased the securities of BioSante during the Class Period as set forth in the certification attached hereto and was damaged as the result of defendants' wrongdoing as alleged in this complaint.

13. Defendant BioSante is a specialty pharmaceutical company focused on developing products for female sexual health and oncology.

14. Defendant Stephen M. Simes ("Simes") is, and at all relevant times has been, the Company's Vice Chairman, President and CEO.

15. Defendant Simes, because of his position with the Company, possessed the power and authority to control the contents of BioSante's quarterly reports, press releases and presentations to securities analysts, money and portfolio managers and institutional investors, *i.e.*, the market. Defendant Simes was provided with copies of the Company's reports and press releases alleged herein to be misleading prior to or shortly after their issuance and had the ability and opportunity to prevent their issuance or cause them to be corrected. Because of his position with the Company, and their access to material non-public information available to them but not to the public, defendant Simes knew that the adverse facts specified herein had not been disclosed to and were being concealed from the public and that the positive representations being made were then materially false and misleading. Defendant Simes is liable for the false statements pleaded herein.

FRAUDULENT SCHEME AND COURSE OF BUSINESS

16. Defendants are liable for: (i) making false statements; or (ii) failing to disclose adverse facts known to them about BioSante. Defendants' fraudulent scheme and course of business

that operated as a fraud or deceit on purchasers of BioSante securities was a success, as it: (i) deceived the investing public regarding BioSante's prospects and business; (ii) artificially inflated the prices of BioSante securities; and (iii) caused plaintiff and other members of the Class to purchase BioSante securities at inflated prices.

BACKGROUND

17. BioSante is a specialty pharmaceutical company focused on developing products for female sexual health, menopause, contraception, and male hypogonadism. Over the past decade, BioSante has been in the process of developing LibiGel, a drug designed to improve the sex drive of women suffering from FSD, and specifically HSDD.

18. HSDD is a persistent lack or absence of sexual desire, fantasies, or thoughts. It is the most common form of female sexual dysfunction. Approximately 43% of women ages 18-59 experience some form of sexual dysfunction. As a result, the anticipated FDA approval of LibiGel was publicized as a huge breakthrough.

19. LibiGel is a gel formulation of testosterone designed to be quickly absorbed through the skin after application on the upper arm, delivering testosterone to the bloodstream evenly over time and in a non-invasive and painless manner. Since the beginning of the Class Period, BioSante had two Phase III clinical trials in progress covered by a Special Protocol Assessment ("SPA") with the FDA, to demonstrate the safety and efficacy of LibiGel, in the treatment of HSDD.[1] All of the defendants' false and misleading statements discussed below involved the efficacy results of LibiGel in the Phase III clinical trials.

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[1] An SPA is a declaration from the FDA that an uncompleted Phase III trial's design, clinical endpoints, and statistical analyses are acceptable for FDA approval. The clinical protocols for Phase III trials can relate to efficacy claims that will be part of an original new drug application ("NDA"), Biologic License Application ("BLA"), or that will be part of an efficacy supplement to an approved NDA or BLA.

DEFENDANTS' FALSE AND MISLEADING STATEMENTS ISSUED DURING THE CLASS PERIOD

20. On February 8, 2010, BioSante issued a press release stating that defendant Simes was interviewed for "Med Tech Sentinel" and featured on its website. During the interview, defendant Simes stated in part:

- LibiGel would be the only drug to treat female sexual dysfunction and the drug was in the last stages of Phase III testing.
- 2009 was transformational for BioSante as it would permit it to complete testing.
- The Company was well-financed.
- The Company would be able to complete enrollment in testing.

21. Within days of these statements, BioSante's stock increased from $1.44 per share to $1.83 per share, an increase of 27%.

22. On February 22, 2010, BioSante issued a press release announcing positive safety data for LibiGel in its Phase III clinical development program. The release stated in part:

> BioSante Pharmaceuticals, Inc., today announced additional positive safety data in its ongoing LibiGel Phase III clinical development program. For the second time, unblinded data have been reviewed by the independent DMC of the LibiGel Cardiovascular and Breast Cancer Safety Study. Based on this review, the DMC once again unanimously recommended continuation of the study as described in the FDA-agreed LibiGel safety study protocol, with no modifications.
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> BioSante reported that the DMC reviewed all unblinded adverse events in the safety study including all serious adverse events and all adverse cardiovascular and breast cancer events in almost 1,200 women-years of exposure. To date, there have been no deaths, only six adjudicated cardiovascular events and only four breast cancers reported. Therefore, in view of the DMC recommendation, the BioSante LibiGel Phase III development program will continue as planned. BioSante targets mid-2011 for submission to the FDA of a new drug application (NDA).
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> Based on this second unblinded positive review by the DMC, we believe that our safety study ultimately will provide the safety data needed for our NDA submission and FDA approval of LibiGel, said Michael Snabes, M.D., Ph.D., BioSante's vice president of clinical development. We have known, based on blinded data, and BioSante remains blinded, that the rates of cardiovascular and breast cancer events in the study continue to be significantly lower than expected in those women enrolled in the safety study, all of whom are at the higher end of cardiovascular risk

for the intended population. If there was a negative effect of testosterone, the cardiovascular rates would be higher. This recommendation by the DMC supports our belief that LibiGel will be safe for the treatment of female sexual dysfunction (FSD) in post-menopausal women, our target patient population. This outcome represents another significant positive advance for our LibiGel clinical development program, Dr. Snabes continued.

The DMC, which for the second time, reviewed the LibiGel safety data on an unblinded basis, confirms what we have learned from the blinded data, that LibiGel does not pose a safety risk to the women in the study, said Stephen M. Simes, BioSante's president and CEO. A DMC can recommend continuing, changing or stopping a study and their main responsibility is to ensure that subjects recruited to the study are not exposed to unnecessary safety risks. Therefore, the DMC's recommendation to continue the LibiGel safety study unchanged is the best possible outcome of the DMC's second unblinded review of all adverse events. This is very good news for BioSante and for women since LibiGel remains the lead pharmaceutical product in the U.S. in active development for the treatment of hypoactive sexual desire disorder (HSDD) in surgically menopausal women. We continue to believe that LibiGel can be the first product approved by the FDA for this common and unmet medical need, also referred to as female sexual dysfunction (FSD).

The Phase III Cardiovascular and Breast Cancer Safety Study is a randomized, double-blind, placebo- controlled, multi-center, cardiovascular events and breast cancer study that will enroll between 2,400 and 3,100 women, exposed to LibiGel or placebo for 12 months. An NDA can be submitted and reviewed by FDA, possibly leading to approval of LibiGel, at that time. After NDA submission and potential approval of LibiGel, BioSante will continue to follow the women enrolled in the study for an additional four years. The LibiGel safety study is tracking a predefined list of cardiovascular events, in agreement with the FDA, including cardiovascular death, myocardial infarction and stroke, in women 50 years of age or older and suffering from at least two cardiovascular risk factors including hypertension and diabetes. The objective of the safety study is to show the relative safety of testosterone compared to placebo in the number of cardiovascular events. The incidence of breast cancer also will be tracked over the course of the study.

In addition to the Phase III Cardiovascular and Breast Cancer Safety Study, BioSante is conducting two LibiGel Phase III efficacy trials. The Phase III efficacy trials of LibiGel in the treatment of FSD are double- blind, placebo-controlled trials that will enroll up to approximately 500 surgically menopausal women each for a six-month clinical trial. The efficacy trials are being conducted under an FDA approved SPA (special protocol assessment agreement).

As previously announced by BioSante, treatment with LibiGel in a Phase II clinical trial significantly increased satisfying sexual events in surgically menopausal women suffering from FSD. The Phase II trial results showed LibiGel significantly increased the number of satisfying sexual events by 238 percent versus baseline ($p<0.0001$); this increase also was significant versus placebo ($p<0.05$). In

this study, the effective dose of LibiGel produced testosterone blood levels within the normal range for pre-menopausal women and had a safety profile similar to that observed in the placebo group. In addition, no serious adverse events and no discontinuations due to adverse events occurred in any subject receiving LibiGel. The Phase II clinical trial was a double-blind, placebo-controlled trial, conducted in the United States, in surgically menopausal women distressed by their low sexual desire and activity.

23. On May 14, 2010, BioSante issued a press release announcing its first quarter financial results and discussing recent developments. The release stated in part:

- **Positive LibiGel® Safety Data in Ongoing Phase III Clinical Development Program**: For the second time, unblinded safety data were reviewed by the independent Data Monitoring Committee (DMC) of the LibiGel Cardiovascular and Breast Cancer Safety Study. The LibiGel safety study continues, with no modifications, based on the excellent safety profile observed to date.

* * *

BioSante incurred a net loss of approximately $10.5 million or $(0.19) per share for the quarter ended March 31, 2010, compared to a net loss of $4.1 million or $(0.15) per share for the same period in 2009. This expected increase in net loss was due primarily to the conduct of the three ongoing LibiGel® (testosterone gel) Phase III clinical studies to support submission of a new drug application (NDA) and U.S. Food and Drug Administration (FDA) approval. The LibiGel Phase III safety and efficacy studies are being conducted under an FDA approved SPA (special protocol assessment)

24. On June 21, 2010, BioSante issued a press release entitled "BioSante Pharmaceuticals Says FDA Advisory Committee Recommendation Against Flibanserin has No Impact on LibiGel®," which stated in part:

"There are important scientific differences between the way LibiGel and flibanserin work on the body, and differences in their clinical development programs," stated BioSante President and CEO Stephen M. Simes. "The LibiGel safety and efficacy trials are being conducted under an SPA (Special Protocol Assessment) agreement with FDA, a level of agreement that the flibanserin program did not have. BioSante also is conducting a large safety study comparing LibiGel to placebo to show cardiovascular and breast-cancer safety. We are pleased also by comments made by the Advisory Committee stressing the need for a product to treat this unmet medical need. Given the recommendation of the Advisory Committee, we believe that LibiGel is positioned to be the first product approved for the treatment of HSDD."

> "The Advisory Committee's judgment on flibanserin has no impact on the clinical development program of LibiGel and is not relevant to the potential for FDA approval of LibiGel for the treatment of HSDD in menopausal women," said Michael C. Snabes, MD, PhD, BioSante's vice president of clinical development

25. On July 13, 2010, BioSante issued a press release entitled "BioSante Pharmaceuticals Announces Initiation of LibiGel® Study to Evaluate its Effect on Cognitive Function in Women," which stated in part:

> "If this study demonstrates that testosterone improves cognitive performance, learning and memory, in healthy older women with normal cognition for their age, as compared to placebo, testosterone may be a potential strategy for the prevention of cognitive decline," said Dr. [Susan] Davis [Professor of Women's Health, Monash University Women's Health Program in Australia].
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> "It is exciting that a new clinical trial has been initiated to evaluate whether testosterone improves memory and learning," said Dr. Michael C. Snabes, BioSante's vice president of clinical development. "Positive results from this new study could provide scientific evidence for an additional advantage of testosterone for menopausal women."

26. On October 18, 2010, BioSante issued a press release entitled "BioSante Pharmaceuticals Reaches Key LibiGel® Safety Study Enrollment Target," which stated in part:

> "This milestone gives BioSante our first opportunity potentially to declare completion of enrollment in the safety study," stated Michael Snabes, M.D., Ph.D., BioSante's senior vice president of medical affairs. "We have had an extremely low number of cardiovascular and breast cancer events to date, as well as three previous favorable DMC recommendations. We expect the study to demonstrate the safety of LibiGel in the treated population, regardless of whether the DMC stops enrollment at 2,500 women or we need to continue enrollment."

27. Subsequently, on October 26, 2010, the Company issued a press release entitled "BioSante Pharmaceuticals Reports Positive LibiGel® Data Monitoring Committee Recommendation – No safety issues observed, study to continue as per protocol without modifications," which stated in part:

> "We are very pleased that the DMC recommended that the study should continue without modification. This means that there are no general or specific safety issues based on their unblinded review of adverse events. The low number of CV events to date is consistent with the safety of testosterone in women," stated Michael Snabes, M.D., Ph.D., the senior vice president of medical affairs for BioSante. "Once

> the DMC determines that there are enough subjects enrolled for statistical significance, enrollment of new subjects into the study will be complete. The current LibiGel safety study protocol allows for up to 4,000 women to be enrolled."
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> * * *
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> "With this most recent favorable DMC recommendation, we continue to believe that LibiGel will be the first product approved by the FDA to treat HSDD in menopausal women, also referred to as FSD," said Stephen M. Simes, BioSante's president & CEO

28. On November 12, 2010, BioSante filed its Form 10-Q with the SEC publicizing the development of its breakthrough new drug for the treatment of HSDD. The Form 10-Q stated in part:

> We believe LibiGel remains the lead pharmaceutical product in the U.S. in active development for the treatment of hypoactive sexual desire disorder (HSDD) in menopausal women, and that it has the potential to be the first product approved by the FDA for this common and unmet medical need, for which presently there is no FDA approved pharmaceutical product. We believe based on agreements with the FDA, including an SPA, that two Phase III safety and efficacy trials and one year of LibiGel exposure in a Phase III cardiovascular and breast cancer safety study with a four-year follow-up post-NDA filing and potentially post-FDA approval and product launch, are the essential requirements for submission and, if successful, approval by the FDA of a new drug application (NDA) for LibiGel for the treatment of FSD, specifically HSDD in menopausal women.

29. On December 27, 2010, BioSante issued a press release entitled "BioSante Pharmaceuticals to Raise $18 Million in Registered Direct Offering," which stated in part:

> BioSante Pharmaceuticals, Inc. today announced that it has received commitments from several institutional investors to purchase $18 million of securities in the a registered direct offering. . . .
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> "We are pleased to have a commitment from these new and existing institutional investors," said Stephen M. Simes, BioSante's president and chief executive officer. "This additional funding from these high quality biotechnology institutional investors provides us with a strong cash position as we close out the year, ensuring our ongoing focus on our LibiGel® Phase III clinical study program. Our objective is to submit a new drug application (NDA) to the U.S. Food and Drug Administration (FDA) by the end of 2011. LibiGel remains the lead pharmaceutical product in the U.S. in active development for the treatment of hypoactive sexual desire disorder (HSDD) in menopausal women, and we continue to believe that LibiGel has the potential to be the first product approved by the FDA for this common and unmet medical need."

30. On this positive news, BioSante's stock jumped, increasing over 26%, to close at $2.00 per share on December 27, 2010.

31. On December 31, 2010, BioSante completed its direct offering for 10.6 million shares of the Company's common stock and warrants to purchase 5.3 million additional shares. This offering resulted in $16.9 million in net proceeds for the Company.

32. On March 4, 2011, BioSante issued a press release announcing another registered direct offering and reiterating and repeating its expectation to be the first company to have a drug approved by the FDA to treat HSDD. The press release stated in part:

> "We are pleased to have this commitment from these new and existing institutional investors," said Stephen M. Simes, BioSante's president and chief executive officer. "This additional funding provides us with added financial power to continue to fund our ongoing LibiGel® Phase III clinical study program. We recently announced completion of enrollment in the first of the two LibiGel Phase III efficacy trials and expect to announce completion of enrollment in the second in the near future. LibiGel remains the lead pharmaceutical product in the U.S. in active development for the treatment of hypoactive sexual desire disorder (HSDD) in menopausal women, and we continue to believe that LibiGel has the potential to be the first product approved by the FDA for this common and unmet medical need."

33. On March 9, 2011, the Company announced the completion of the direct offering of an aggregate of approximately 12.2 million shares of the Company's common stock and warrants to purchase an additional 4.0 million shares, resulting in net proceeds of $23.8 million.

34. On March 16, 2011, BioSante issued a press release announcing its financial results for 2010 and additionally reported on the Company's clinical development. The release stated in part:

> "We are very pleased with our progress over the last year as well as our current cash balance," said Stephen M. Simes, BioSante's president and CEO. "Through careful cash management and our financing strategy, we believe we now have removed any near-term financial risk from BioSante, and our current cash balance is sufficient to finance our operations and LibiGel clinical development well into 2012, without need for additional funds."

* * *

LibiGel® Clinical Highlights

The increased LibiGel clinical development expenses during 2010 was the result of steady progress in BioSante's LibiGel Phase III clinical program. LibiGel is in development for the treatment of female sexual dysfunction (FSD), specifically, hypoactive sexual desire disorder (HSDD) in menopausal women, for which there is no FDA-approved product. In February 2011, the company announced completion of enrollment in the first of two LibiGel Phase III efficacy trials, and expects enrollment in the second efficacy trial to be completed in the near future. BioSante continues to expect data from the two efficacy trials in Fall 2011

35. Subsequently on March 16, 2011, BioSante filed its Form 10-K with the SEC announcing the requirements remaining for submission and approval of LibiGel by the FDA. The Form 10-K stated in part:

We believe LibiGel remains the lead pharmaceutical product in the U.S. in active development for the treatment of hypoactive sexual desire disorder (HSDD) in menopausal women, and that it has the potential to be the first product approved by the FDA for this common and unmet medical need. We believe based on agreements with the FDA, including an SPA, that two Phase III safety and efficacy trials and a minimum average exposure to LibiGel per subject of 12 months in a Phase III cardiovascular and breast cancer safety study with a four-year follow-up post-NDA filing and potentially post-FDA approval and product launch, are the essential requirements for submission and, if successful, approval by the FDA of a new drug application (NDA) for LibiGel for the treatment of FSD, specifically HSDD in menopausal women. Currently, three LibiGel Phase III studies are underway: two LibiGel Phase III safety and efficacy clinical trials under an FDA agreed SPA and one Phase III cardiovascular and breast cancer safety study. We have completed enrollment in the first efficacy trial and plan to complete enrollment in the second efficacy trial in the near future. The Phase III safety study is currently enrolling women, and as of the end of February 2011 had enrolled approximately 2,900 women. In February 2011, we announced that based upon the fifth review of study conduct and unblinded safety data from the safety study by the study's independent data monitoring committee (DMC), the DMC unanimously recommended continuing the safety study as described in the FDA-agreed study protocol, with no modifications. If enrollment is not completed sooner, enrollment will continue until the safety study reaches its predetermined maximum of 4,000 women. Upon completion of the statistical analyses of the safety study and efficacy trials, we intend to submit an NDA to the FDA, requesting approval to market LibiGel for the treatment of HSDD in menopausal women. It is our objective to submit the LibiGel NDA to the FDA so that LibiGel may be approved in 2012.

* * *

We believe LibiGel remains the lead pharmaceutical product in the U.S. in active development for the treatment of HSDD in menopausal women, and that it has

> the potential to be the first product approved by the FDA for this common and unmet medical need. We believe based on agreements with the FDA, including an SPA, that two Phase III safety and efficacy trials and a minimum average exposure to LibiGel per subject of 12 months in a Phase III cardiovascular and breast cancer safety study with a four-year follow-up post-NDA filing and potentially post-FDA approval and product launch, are the essential requirements for submission and, if successful, approval by the FDA of an NDA for LibiGel for the treatment of FSD, specifically HSDD in menopausal women. We have three SPAs in place concerning LibiGel. The first SPA agreement covers the pivotal Phase III safety and efficacy trials of LibiGel in the treatment of FSD for "surgically" menopausal women. The second SPA covers our LibiGel program in the treatment of FSD in "naturally" menopausal women. The third SPA agreement covers the LibiGel stability, or shelf life, studies for the intended commercialization of LibiGel product.

36. On March 30, 2011, BioSante issued a press release entitled "BioSante Pharmaceuticals Completes Enrollment in Both Pivotal LibiGel® Phase III Efficacy Trials," which stated in part:

> BioSante Pharmaceuticals, Inc. today announced that enrollment of subjects in the second of two pivotal Phase III LibiGel (testosterone gel) safety and efficacy trials has been completed. Enrollment in the first LibiGel efficacy trial was completed in February. The efficacy trials are being conducted under an FDA-approved special protocol assessment (SPA) agreement. LibiGel is in development for the treatment of female sexual dysfunction (FSD), specifically, hypoactive sexual desire disorder (HSDD) in menopausal women, for which there is no FDA-approved product.
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> "This is an important achievement for BioSante and a key step toward completing the LibiGel Phase III clinical development program," said Joanne Zborowski, BioSante's vice president of clinical development. "There are more than 1,000 subjects in the efficacy trials and we anticipate announcing top-line efficacy data this fall. In addition, we have over 3,000 subjects enrolled in our LibiGel Phase III safety study," she added.
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> Phillip B. Donenberg, BioSante's senior vice president of finance & CFO commented, "This key LibiGel achievement, coupled with our successful financing strategy, guarantees a solid timeline for Phase III efficacy data, with sufficient funds to finance our operations and LibiGel clinical development through that data and well into 2012. As a result, we have removed near-term financial risk from BioSante without the need for additional funds."

37. On May 31, 2011, BioSante issued a press release supporting its prospects of creating the first product approved by the FDA for the treatment of HSDD by hyping a "90 percent predictive probability of success." The release stated in part:

> "LibiGel remains the only product in the world in Phase III clinical development for the treatment of HSDD," said Stephen M. Simes, BioSante's president & CEO. "The ability to stop enrollment as per the sample size analysis that indicates a 90 percent predictive probability of success is very encouraging for the outcome of our LibiGel Phase III clinical development program. With this most recent development, we continue to believe that LibiGel will be the first product approved by the FDA to treat HSDD, also referred to as FSD, in menopausal women."

38. As a result of this news, the Company's stock continued to trade at artificially inflated prices during the Class Period. BioSante stock reached a high of $3.81 on July 12, 2011, an increase of nearly 150% compared to the price of the stock before the defendants' false and misleading statements.

39. On August 5, 2011, BioSante filed its Form 10-Q with the SEC, which represented that "LibiGel remains the most clinically advanced pharmaceutical product in the U.S." The Form 10- Q stated in part:

> We believe LibiGel remains the most clinically advanced pharmaceutical product in the U.S. in active development for the treatment of hypoactive sexual desire disorder in menopausal women, and that it has the potential to be the first product approved by the FDA for this common and unmet medical need.

40. In August 2011, the Company completed its third offering of the Class Period for an aggregate of 16 million shares of common stock. Defendants raised $45 million in net proceeds from this underwritten public offering.

41. Then, on December 14, 2011, BioSante issued a press release disclosing for the first time to investors that LibiGel had failed to yield positive results in large-scale efficacy tests designed by the Company. According to the clinical trial results, women treated with LibiGel did not experience a statistically significant increase in either total satisfying sexual encounters or sexual desire. In fact, in the double-blind, placebo-controlled trial, LibiGel did not fare significantly better than the placebo. The release stated in part:

> "We obviously are very disappointed by the Phase III LibiGel efficacy trial results. We have been committed to LibiGel for many years and we are committed to

> determining the future of LibiGel," stated Stephen M. Simes, BioSante's president & CEO. "We will continue to analyze the efficacy trial data fully and determine plans for our next steps in the LibiGel development plan, and provide an update at a later time. While the LibiGel Phase III cardiovascular and breast cancer safety study currently continues as planned, we will be analyzing the best path forward for the study given the results reported today. I want to thank our entire BioSante clinical team and the clinical investigators for their tireless efforts in these trials, and I also want to thank the women enrolled in the BLOOM trials for their participation."

42. On this news, BioSante's stock collapsed $1.64 per share to close at $0.48 per share on December 15, 2011, a one-day decline of over 77% on volume of nearly 50 million shares.

43. On December 15, 2011, Jefferies & Co. issued an analyst report downgrading BioSante to "Hold." The report provided in part:

> BPAX announced top-line LibiGel Ph III data, and in a surprise, missed on all 6 efficacy endpoints. Given the magnitude of the miss, the LibiGel story seems to be done; thus we now remove all LibiGel-related revenue from our model.

44. The negative clinical trial results came as a big surprise, as there was consensus emerging in the market that the drug had a 70%-80% probability of approval. Defendants caused the market to believe that most of the negatives were safety-related and that efficacy was almost a foregone conclusion. In fact, of the eight analysts who covered the stock, five rated it a strong buy and three a buy; no holds, no underperforms, and no sells. And the median price target was $5.88, with high targets ranging between $7 and $8.

45. On December 14, 2011, BioSante's shares plummeted as a result of this news. After recently trading as high as $2.52 per share on December 13, 2011, shares of BioSante's common stock closed on December 19, 2011, at just $0.38 per share.

46. The true facts, which were known by the defendants but concealed from the investing public during the Class Period, were as follows:

(a) LibiGel's efficacy was well short of that required to obtain FDA approval; and

(b) LibiGel failed to yield statistically superior results to placebo.

47. As a result of defendants' false statements, BioSante's stock traded at inflated levels during the Class Period. However, after the above revelations seeped into the market, the Company's shares were hammered by massive sales, sending them down over 87% from their Class Period high.

LOSS CAUSATION

48. During the Class Period, as detailed herein, the defendants made false and misleading statements and engaged in a scheme to deceive the market and a course of conduct that artificially inflated the price of BioSante securities and operated as a fraud or deceit on Class Period purchasers of BioSante securities by misrepresenting the Company's business and prospects. Later, when the defendants' prior misrepresentations and fraudulent conduct became apparent to the market, the prices of BioSante securities fell precipitously, as the prior artificial inflation came out of the prices over time. As a result of their purchases of BioSante securities during the Class Period, plaintiff and other members of the Class suffered economic loss, *i.e.*, damages, under the federal securities laws.

NO SAFE HARBOR

49. BioSante's verbal "Safe Harbor" warnings accompanying its oral forward-looking statements ("FLS") issued during the Class Period were ineffective to shield those statements from liability.

50. The defendants are also liable for any false or misleading FLS pleaded because, at the time each FLS was made, the speaker knew the FLS was false or misleading and the FLS was authorized and/or approved by an executive officer of BioSante who knew that the FLS was false. None of the historic or present tense statements made by defendants were assumptions underlying or relating to any plan, projection or statement of future economic performance, as they were not stated to be such assumptions underlying or relating to any projection or statement of future economic

performance when made, nor were any of the projections or forecasts made by defendants expressly related to or stated to be dependent on those historic or present tense statements when made.

CLASS ACTION ALLEGATIONS

51. Plaintiff brings this action as a class action pursuant to Rule 23 of the Federal Rules of Civil Procedure on behalf of all persons who purchased or otherwise acquired BioSante securities during the Class Period (the "Class"). Excluded from the Class are defendants and their families, the officers and directors of the Company, at all relevant times, members of their immediate families and their legal representatives, heirs, successors or assigns and any entity in which defendants have or had a controlling interest.

52. The members of the Class are so numerous that joinder of all members is impracticable. The disposition of their claims in a class action will provide substantial benefits to the parties and the Court. BioSante has over 109 million shares of stock outstanding, owned by hundreds if not thousands of persons.

53. There is a well-defined community of interest in the questions of law and fact involved in this case. Questions of law and fact common to the members of the Class which predominate over questions which may affect individual Class members include:

(a) whether the 1934 Act was violated by defendants;

(b) whether defendants omitted and/or misrepresented material facts;

(c) whether defendants' statements omitted material facts necessary to make the statements made, in light of the circumstances under which they were made, not misleading;

(d) whether defendants knew or deliberately disregarded that their statements were false and misleading;

(e) whether the prices of BioSante securities were artificially inflated; and

(f) the extent of damage sustained by Class members and the appropriate measure of damages.

54. Plaintiff's claims are typical of those of the Class because plaintiff and the Class sustained damages from defendants' wrongful conduct.

55. Plaintiff will adequately protect the interests of the Class and has retained counsel who are experienced in class action securities litigation. Plaintiff has no interests which conflict with those of the Class.

56. A class action is superior to other available methods for the fair and efficient adjudication of this controversy.

COUNT I

For Violation of §10(b) of the 1934 Act and Rule 10b-5 Against All Defendants

57. Plaintiff incorporates ¶¶1-56 by reference.

58. During the Class Period, defendants disseminated or approved the false statements specified above, which they knew or deliberately disregarded were misleading in that they contained misrepresentations and failed to disclose material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading.

59. Defendants violated §10(b) of the 1934 Act and Rule 10b-5 in that they:

(a) employed devices, schemes and artifices to defraud;

(b) made untrue statements of material facts or omitted to state material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading; or

(c) engaged in acts, practices and a course of business that operated as a fraud or deceit upon plaintiff and others similarly situated in connection with their purchases of BioSante securities during the Class Period.

60. Plaintiff and the Class have suffered damages in that, in reliance on the integrity of the market, they paid artificially inflated prices for BioSante securities. Plaintiff and the Class would not have purchased BioSante securities at the prices they paid, or at all, if they had been aware that the market prices had been artificially and falsely inflated by defendants' misleading statements.

COUNT II

For Violation of §20(a) of the 1934 Act
Against All Defendants

61. Plaintiff incorporates ¶¶1-60 by reference.

62. Defendant Simes acted as controlling person of BioSante within the meaning of §20(a) of the 1934 Act. By virtue of his position with the Company, and ownership of BioSante stock, defendant Simes had the power and authority to cause BioSante to engage in the wrongful conduct complained of herein. BioSante controlled defendant Simes and all of its employees. By reason of such conduct, defendants are liable pursuant to §20(a) of the 1934 Act.

PRAYER FOR RELIEF

WHEREFORE, plaintiff prays for judgment as follows:

A. Declaring this action to be a proper class action pursuant to Fed. R. Civ. P. 23;

B. Awarding plaintiff and the members of the Class damages, including interest;

C. Awarding plaintiff's reasonable costs and attorneys' fees; and

D. Awarding such equitable/injunctive or other relief as the Court may deem just and proper.

JURY DEMAND

Plaintiff demands a trial by jury.

DATED: February 21, 2012

ROBBINS GELLER RUDMAN
& DOWD LLP
JAMES E. BARZ (IL Bar # 6255605)

s/James E. Barz
JAMES E. BARZ (IL Bar # 6255605)

200 South Wacker Drive, 31st Floor
Chicago, IL 60606
Telephone: 312/674-4674
312/674-4676 (fax)

ROBBINS GELLER RUDMAN
& DOWD LLP
DARREN J. ROBBINS
DAVID C. WALTON
655 West Broadway, Suite 1900
San Diego, CA 92101
Telephone: 619/231-1058
619/231-7423 (fax)

CHAPIN FITZGERALD SULLIVAN
& BOTTINI LLP
FRANCIS A. BOTTINI
550 West C Street, Suite 2000
San Diego, CA 92101
Telephone: 619/241-4810
619/955-5318 (fax)

Attorneys for Plaintiff

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